510(k) Summary

FEB 2 1 2013

Date of Summary: February 20, 2013

Submitted by:

Submitter: Caldera Medical, Inc.
Address: 5171 Clareton Drive
Agoura Hills, CA 91301
Contact: Vicki Gail, Manager QA/RA
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Device Information:

Device Trade Name: Vertessa™ Lite

Classification: Class II, Product Code: OTO, Surgical Mesh, Gynecologic, 21 CFR 878.3300, General and Plastic Surgery

Predicate: Vertessa™ (K120327), Caldera Medical, Inc.

Description of Device:

Vertessa™ Lite devices are designed to be used in women suffering from uterine or vaginal vault prolapse and are implanted or affixed using suture of the surgeon's choice. Vertessa™ Lite devices are provided sterile and are comprised of macroporous monofilament polypropylene warp knit blue mesh. Vertessa™ Lite will be available in a two rectangular flat sheet mesh designs.

Intended Use of Device:

Vertessa™ Lite devices may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.

Technological Characteristics

Vertessa™ Lite devices are a modification of the predicate mesh device, Vertessa™ in knit pattern and mesh resin colorant. In addition, Vertessa™ Lite is available in two sizes. Vertessa™ Lite has the same intended use as that of its predicate, Vertessa™ and does not change the fundamental scientific technology of the predicate device.

Performance Summary

In accordance with the *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh,* the following mesh characteristics were assessed on Vertessa™ Lite: mesh thickness, mesh knit characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels. The results from testing demonstrate substantial equivalence to the predicate device, Vertessa™.

Results of mechanical bench and validation testing demonstrate Vertessa™ Lite device function equivalence based upon key device characteristics and its intended use to the predicate device, Vertessa™.

A reference device which is also a product of Caldera Medical, Ascend® Blue (K101462), was used as support for Vertessa™ Lite biocompatibility since both are comprised of the same polypropylene mesh resin with colorant. Ascend® Blue has passed all biocompatibility as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 3. Biocompatibility* and FDA *Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".*

Sterility of Vertessa™ Lite devices was tested in accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1* and met all requirements.

Vertessa™ Lite devices have passed all testing requirements in terms of aging and shelf life in accordance with the FDA guidance, *Final Guidance for Industry, FDA, FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 4. Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

Summary of Substantial Equivalence

The conclusions drawn from non-clinical testing, demonstrate that Vertessa™ Lite is safe and effective for its intended use and is substantially equivalent to the predicate device, Vertessa™, also a product of Caldera Medical, in its intended use, performance and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2013

Caldera Medical, Inc.
% Ms. Vicki Gail
QA/RA Manager
5171 Clareton Drive
AGOURA HILLS CA 91301

Re: K123337
Trade/Device Name: Vertessa™ Lite
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTO
Dated: January 24, 2013
Received: February 1, 2013

Dear Ms. Gail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

CALDERA MEDICAL

Statement of Indications For Use

Indications For Use

510 (k) Number (if known): K123337

Device Name: Vertessa™ Lite

Indications for Use:

Vertessa™ Lite may be used for the repair of uterine or vaginal vault prolapse that require support material. It may be used in open or laparoscopic abdominal procedures.

Prescription Use --X-- AND/OR Over the Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123337

Benjamin R. Fisher -S
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